



**DEPARTMENT OF TRANSPORTATION**

**[ 4910-EX-P ]**

**Federal Motor Carrier Safety Administration**

**[Docket No. FMCSA-2012-0081]**

**Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillators**

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of application for exemption; request for comments.

**SUMMARY:** FMCSA announces receipt of applications from 15 individuals for an exemption from the cardiovascular standard [49 CFR 391.41(b)(4)]. These 15 individuals are requesting an exemption due to the presence of implantable cardioverter defibrillators (ICD) as a result of their underlying cardiac condition. Of the 15 individuals requesting exemptions, three individuals (Craig Bohms, James Dean, and Mark Steiner) were previously published in a January 2014 **Federal Register** under the docket listed above. A final decision was not issued on these three individuals because the Agency was in the process of gathering and analyzing additional data concerning ICDs and commercial motor vehicle (CMV) driving. These three individuals are being published again with 12 new individuals. If granted, an exemption would enable these individuals with ICDs to operate CMVs for up to 2 years in interstate commerce.

**DATES:** Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA-2012-0081 using any of the following methods:

- Federal eRulemaking Portal: Go to [www.regulations.gov](http://www.regulations.gov). Follow the

on-line instructions for submitting comments.

- Mail: Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE, West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.
- Hand Delivery or Courier: West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- Fax: 1-202-493-2251.

Each submission must include the Agency name and the docket ID for this Notice. Note that DOT posts all comments received without change to [www.regulations.gov](http://www.regulations.gov), including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to [www.regulations.gov](http://www.regulations.gov), at any time or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue, SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 USC 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to [www.regulations.gov](http://www.regulations.gov), as described in the system records notice (DOT/ALL-14 FDMS), which can be reviewed at [www.dot.gov/privacy](http://www.dot.gov/privacy).

**FOR FURTHER INFORMATION CONTACT:** Charles A. Horan, III, Director, Office of

Carrier, Driver and Vehicle Safety, (202) 366-4001, or via email at [fmcsamedical@dot.gov](mailto:fmcsamedical@dot.gov), or by letter to FMCSA, Room W64-113, Department of Transportation, 1200 New Jersey Avenue, SE, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

### **Submitting Comments**

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission. To submit your comment online, go to <http://www.regulations.gov> and in the search box insert the docket number “FMCSA-2012-0081” and click the search button. When the new screen appears, click on the blue “Comment Now!” button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change this proposed rule based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

### **Viewing Comments and Documents**

To view comments, as well as any documents mentioned in this notice, or to submit your comment online, go to [www.regulations.gov](http://www.regulations.gov) and in the search box insert the docket number

“FMCSA-2012-0081” and click “Search.” Next, click “Open Docket Folder” and you will find all documents and comments related to the proposed rulemaking.

## **SUPPLEMENTARY INFORMATION:**

### **Background**

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** [49 CFR 381.315(a)]. The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The Agency may grant an exemption subject to specified terms and conditions. The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

The FMCSA provides medical advisory criteria for use by medical examiners in determining whether drivers with certain medical conditions should be certified to operate CMVs in interstate commerce. The advisory criteria are currently set out as part of the medical examination report published with 49 CFR 391.43. The advisory criteria for section 391.41(b)(4)

indicate that the term “has no current clinical diagnosis of” is specifically designed to encompass: “*a clinical diagnosis of*” (1) a current cardiovascular condition, or (2) a cardiovascular condition which has not fully stabilized regardless of the time limit. The term “*known to be accompanied by*” is designed to include a clinical diagnosis of a cardiovascular disease (1) which is accompanied by symptoms of syncope, dyspnea, collapse or congestive cardiac failure; and/or (2) which is likely to cause syncope, dyspnea, collapse, or congestive cardiac failure.

### **Summary of Applications**

#### *Craig Bohms*

Mr. Bohms is a 57-year old Class A CDL holder in Illinois. Mr. Bohms documents that his ICD was implanted in 2013. A March 13, 2015, letter from his cardiologist reports Mr. Bohms “is doing well feeling good and has not needed or had any shock therapy from his defibrillator. He is stable from a heart rhythm standpoint and may drive for his job from that standpoint.”

#### *James Dean*

Mr. Dean is a 55-year old from Wisconsin. A November 2014 medical document received from Mr. Dean indicates that his ICD was implanted in August of 2007. An April 2014 routine in-clinic visit document indicates no ventricular tachycardia episodes detected and that the patient states feeling well with no dizziness or syncope. A March 2014 document from St. Mary’s Hospital indicates Mr. Dean has a rate responsive dual chamber ICD.

#### *Daniel Donahue*

Mr. Donahue is a 72-year old Class A CDL holder in Wisconsin. A February 4, 2015 letter from his cardiologist reports that Mr. Donahue’s ICD was implanted in December 2004. “[Mr. Donahue] has never required any therapy from his ICD. Since September 2013 to the date of this letter, [Mr. Donahue] has only one event of ventricular tachycardia which lasted 7 seconds,

and did not require any therapy from his ICD. His ejection fraction has improved to 42% on his last echocardiogram which was done in September 2013.”

*Bernard Fritzson*

Mr. Fritzson is a 56-year old Class A CDL holder in Kansas. A February 16, 2015 letter from his cardiologist reports that “[Mr. Fritzson] received an ICD for secondary prevention due to non-ischemic cardiomyopathy, and atrial fibrillation. The device was implanted for secondary prevention after witnessed ventricular tachycardia during a cardiac procedure. Mr. Fritzson’s last documented shock from his ICD was in April 2014. He has received 3 total inappropriate shocks for atrial fibrillation with rapid ventricular response. He is on optimal medical therapy for his condition and is stable from a cardiac standpoint.”

*Terry Goodhile*

Mr. Goodhile is a 56-year old from Pennsylvania. A December 2014 medical form from St. Luke’s Occupational Medicine reports that he has “hypertrophic cardiomyopathy with ICD.” The report states that “he is medically stable and is closely monitored by the provider and his cardiologist every 3 months.” Mr. Goodhile reports in a letter that his “ICD was implanted in April 2013 and has never delivered a shock.”

*Ronald Heinlein*

Mr. Heinlein is a 55-year old from California. His dual chamber ICD was implanted in 2008. A February 6, 2015, letter from his cardiologist reports that his device is “for the purpose of life saving as a back-up, and that the device has never been used and may never be used.”

*David Jensen*

Mr. Jensen is a 52-year old from California. A February 2, 2015, letter from his cardiologist states that his ICD was “placed in 2011 and he has had no device firings and no

clinical events or arrhythmias. He is not prone to syncopal episodes and has never had any in the past. He engages in other high risk activities such as parachuting and hang gliding.” His cardiologist reports “there is no contraindication to holding a motor vehicle license for either commercial or non-commercial vehicles based on the presence of his ICD.”

*Douglas Lopez*

Mr. Lopez is a 32-year old from New York. His ICD was implanted in 2011. A February 6, 2015, letter from his cardiologist reports that Mr. Lopez’s “device has never fired. His underlying cardiac condition is well compensated and stable with therapy.” Mr. Lopez wrote in a letter to the FMCSA that he plays sports, coaches various children’s athletics, and would be considered an extremely active individual. If granted an exemption, Mr. Lopez would like to resume driving a truck in interstate commerce.

*Leslie Mitchell*

Mr. Mitchell is a 55-year old Class A CDL holder in Minnesota. He has a pacemaker ICD/defibrillator that was implanted in March 2014. In July 2014 his cardiologist wrote that “Mr. Mitchell has had near complete recovery of his heart function thanks in part to medication and pacemaker therapy. We have seen no evidence concerning heart arrhythmias and he does not require defibrillator therapy.” In August 2014 his cardiology specialists wrote that “due to his improved cardiac status the tachycardia therapy portion of his biventricular Internal Cardiac Defibrillator was disabled (as recommended by his physicians). The biventricular pacing (pacemaker) portion of his CRT-D device remains functional.”

*Michael Politz*

Mr. Politz is a 50-year old non-CDL holder from Washington State. A March 2014 letter from his cardiologist reports that Mr. Politz had a defibrillator implanted “in 2012 for a primary

ventricular fibrillation. A stress test in Jan 2013 demonstrated ejection fraction of 40%, inferior scar but no ischemia. He has had no recurrences of hemodynamically significant dysrhythmias by monitoring on his implantable defibrillator and no syncope, near syncope, or shocks. His cardiologist's letter states that he is at a relatively low risk for recurrent episodes as he has been revascularized." If granted an exemption, Mr. Politz would like to resume driving a truck in interstate commerce.

Mark Register

Mr. Register is a 46-year old Class B CDL holder in North Carolina. An October 2014 affidavit from his cardiologist reports that his ICD "was implanted in 2010 for a documented ventricular arrhythmia. Mr. Register's ventricular arrhythmia was determined to be a Right Ventricular Outflow Tract ventricular tachycardia which was treated by ablation in May 2011. His cardiologist is 99.5% confident that the source of Mr. Register's original cardiac arrhythmia has been corrected and removed. Mr. Register has been clinically stable since that time and has experienced no malignant ventricular arrhythmias. His defibrillator is medically checked every three months to ensure proper function and is "nothing more than a back-up or "safety net." His cardiologist's professional medical opinion is that Mr. Register "is completely and physically capable of operating a commercial motor vehicle" and "poses no risk in operating a commercial motor vehicle." His cardiologist cites three recent scholarly articles from the Journal of American College of Cardiology and the European Society of Cardiology, which conclude that "patients with defibrillators are able to operate motor vehicles just as safely if not more so than the general population."

Charles Rhodes

Mr. Rhodes is a 59-year old from Arizona. Mr. Rhodes provided medical reports from



2013-2014 from his cardiologists indicating his ICD was implanted in February 2013. An October 22, 2014, medical history from his cardiologist reports that he follows up regularly in the pacemaker clinic every 3 months.

Mark Steiner

Mr. Steiner is a 65-year old from Ohio. A January 29, 2015, letter from his cardiologist states that his ICD was implanted in 2012 for primary prevention. An ICD interrogation conducted on January 29, 2015, showed no report of any dysrhythmias or requirement for anti-tachycardia pacing or defibrillation. His cardiologist states Mr. Steiner has had no chest, neck, jaw or arm discomfort, pedal edema, near syncope, syncope, or ICD discharge. If granted an exemption, Mr. Steiner would like to resume driving a truck in interstate commerce

Stephen Watts

Mr. Watts is a 52-year old Class A CDL holder in Kansas. A December 2014 letter from his cardiologist reports that his ICD was implanted in 2013. According to a January 2015 letter from his cardiologists, “from a clinical standpoint he is doing quite well. He has not had any shortness of breath, PND or orthopnea. Review of his pacemaker/defibrillator shows that he has not had any significant dysrhythmias.” A November 2014 letter from his employer states that he has “driven over 1 million accident free miles.” If granted an exemption, Mr. Watts would like to resume driving a truck in interstate commerce.

John Allen Weltz

Mr. Weltz is a 51-year old Class A CDL holder in Nebraska. A February 2, 2015, letter from his cardiologist reports that Mr. Weltz received an ICD on February 28, 2014, and from Mr. Weltz’s records, his cardiologist does not think he has been shocked. A September 2014 letter from his cardiologist states, “He has had no ventricular arrhythmias since his ICD was implanted

and he is quite stable.” Mr. Weltz reports that for the past 10 years he has been keeping in close contact with all of his doctors, keeping all of his medical appointments and taking all medication as prescribed.

### **Request for Comments**

In accordance with 49 U.S.C. 31315 and 31136(e), FMCSA requests public comment from all interested persons on the exemption applications described in this notice. We will consider all comments received before the close of business on the closing date indicated earlier in the notice

**Issued on: April 14, 2015.**

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Larry W. Minor,  
Associate Administrator for Policy.

[FR Doc. 2015-09068 Filed: 4/20/2015 08:45 am; Publication Date: 4/21/2015]